

Remarks

Claims 1-13 are presented for the Examiner's review and consideration. In this Response, claim 4 is amended. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §112 Rejection

Claim 4 was rejected under 35 U.S.C. §112, second paragraph. The phrase "for example" was cited as rendering the claim indefinite. Accordingly, Applicant has amended claim 4 to remove reference to the phrase "for example" in favor of Markush language.

Applicant respectfully submits that the amendment does not introduce new matter.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the §112 rejection.

35 U.S.C. §103 Rejections

Claims 1-13 were rejected under 35 U.S.C. §103(a), as being unpatentable over Buchholz et al. (U.S. Patent 6,514,973 B1) ("Buchholz") in view of Scott (U.S. Patent Publication 2002/0150632 A1) ("Scott") and Smith (U.S. Patent Publication 2005/0244510 A1). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Buchholz

Buchholz discloses compositions for the treatment and prevention of transmethylation disorders, in particular neurological and pathopsychological diseases. *See* column 1, lines 6-8. The compositions contain three active ingredients; component A: one or more phosphatidyl

serines, component B: one or more methyl transporters, and component C: one or more compounds selected from methyl and methylene donors, provided that the phosphatidyl serines and compounds with methyl transporting properties do not form part of component C. *See* abstract and claim 1. These compositions are useful for reducing elevated levels of homocysteine found in transmethylation disorders. *See* column 1, line 37 to column 2, line 12.

Buchholz states that it has been documented that oral supplementation with 200 to 300 mg of phosphatidyl serines per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate especially in aging people and in patients with certain neurological and pathopsychological conditions. *See* column 2, lines 22-27. However, Buchholz discloses only the addition of 50 mg of phosphatidyl serine in the described composition. *See* Example 1.

Buchholz does not discuss any connection or relationship between glucose intake and phosphatidyl serine (in the brain) other than to mention that it has been assumed that phosphatidyl serines are able to stimulate glucose metabolism in the brain. *See* column 2, lines 32-34.

Buchholz discloses that the compositions are suitable as a food or food supplement and discusses preparing such compositions by combining the active ingredients with edible “nutritional substances”, including carbohydrates. The addition of “nutritional substances” to the compositions is disclosed as optional. *See* column 5, lines 40-49.

Scott

Scott discloses a treatment for substance abuse, in particular a method for reducing cravings associated with habitual, chronic chemical substance abuse or addiction in humans by administering a composition, containing nutrients from four nutritional subgroups; B vitamins, minerals, lipids, and neurologically active amino acids, that functions primarily to boost neurochemical levels. *See* abstract and paragraphs [0001], [0007], and [0009]-[0013]. Scott teaches phosphatidyl serine as one of the ingredients of the composition and further discloses

that phosphatidyl serine is known to boost serotonin levels. *See* abstract and paragraph [0006]. However, Scott does not disclose a specific amount of phosphatidyl serine to be included in the composition, but refers only to an “effective amount” or a “therapeutically-effective amount.” *See* abstract and claim 1. Scott discusses the relationship between neurotransmitter levels and energy (glucose) metabolism in the brain by stating: If the brain is deficient in certain nutrients, for example, folic acid, glucose metabolic efficiency is hindered resulting in a concomitant decrease in cognitive efficiency. *See* paragraph [0018]. However, no mention is made of glucose intake or addition of carbohydrates to the described compositions.

Smith

Smith discloses compositions formulated to provide support for mental performance and/or improve mental performance through the elimination of mental fatigue, as well as to improve memory, focus, and concentration. *See* abstract and paragraph [0014]. Smith teaches numerous benefits of supplemental phosphatidyl serine, for example, increased levels of acetylcholine and dopamine, improved memory, mood, behavior, and learning ability, and decreased depression. *See* paragraphs [0045]-[0047]. Smith discloses phosphatidyl serine as a component of the compositions and teaches that amounts of about 40 mg to about 100 mg are most preferable for use. *See* paragraph [0047]. 44 mg of phosphatidyl serine is exemplified in Formulations I and II. *See* Table 1 and paragraphs [0084]–[0087]. Smith does not disclose carbohydrates as an active ingredient and teaches the addition of carbohydrates only as necessary to prepare the formulations for administration.

Present Invention

In contrast, the present invention discloses a food item, preferably a bar of chocolate, that has a phosphatidyl serine content of 100 mg to 300 mg and a relatively high carbohydrate content. *See* abstract.

The starting point of the present invention is the discovery that, in older individuals, the intake of 100 mg to 300 mg of phosphatidyl serine per day can lead to an improvement of the cognitive functional capacity, in particular the memory and learning capacity, and to an increase in the powers of concentration and attentiveness. *See* paragraph [0010].

Preferably, the food product according to the present invention has a relatively high carbohydrate content, such as fructose syrup, sugar and/or glucose syrup. By specifically combining the intake of carbohydrates and phosphatidyl serine, the glucose intake, and thus the glucose content in the brain cells, is markedly increased. In the short term, this makes possible an especially marked increase in the cognitive functional capacity. The minimum quantity of carbohydrates is preferably 15 g combined with preferably 100 to 300 mg of phosphatidyl serine. *See* paragraph [0018].

Eating one or more of the chocolate bars every day in the short term leads to an increase in the cognitive functional capacity after consumption of the bar, on the one hand, and in the long term to a lasting improvement of the cognitive functions which begins to be noticeable, for example, after a period of one to three weeks. Thus, improvements both with respect to ARCD [Age Related Cognitive Decline] and with respect to AAMI [Age Associated Memory Impairment] can be reached. *See* paragraph [0050].

Thus, the present invention is a food product that specifically combines the intake of phosphatidyl serine with the intake of carbohydrates. Applicant found this combination to improve cognitive function shortly after consumption, as well as lasting improvements over time. Neither this combination nor the results are suggested in the prior art. Buchholz teaches the addition of carbohydrates only as an optional nutritional substance. Scott does not teach the addition of carbohydrates to his compositions. And Smith teaches the addition of carbohydrates only as necessary to prepare his formulations for administration.

Furthermore, the instant application claims priority under 35 U.S.C. § 119(e) to Austrian Patent Application A 482/2001, filed on March 26, 2001. A certified copy of this document was filed on February 15, 2008. Thus, the priority date of the instant application is March 26, 2001.

The Scott reference, U.S. Patent Publication 2002/0150632 A1, is based upon provisional application 60/268,007, filed on April 12, 2001. The Smith reference, U.S. Patent Publication 2005/0244510 A1, is based upon provisional application 60/302,653, filed on July 5, 2001. Therefore, Applicant respectfully submits that Scott (U.S. Patent Publication 2002/0150632 A1) and Smith (U.S. Patent Publication 2005/0244510 A1) are not prior art with regard to the instant invention.

Accordingly, Applicant respectfully submits that claims 1-13 are patentable over Buchholz in view of Scott and Smith.

In light of the foregoing arguments, Applicant requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Claims 1-13 were rejected under 35 U.S.C. §103(a), as being unpatentable over Lang et al. (U.S. Patent Publication 2003/0161861 A1) (“Lang”) in view of Strumor et al. (U.S. Patent 6,149,939) (“Strumor”) and further in view of Scott (U.S. Patent Publication 2002/0150632 A1) (“Scott”) and Smith (U.S. Patent Publication 2005/0244510 A1). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Lang

Lang discloses the use of a cereal product such as a biscuit or cracker having a slowly digestible starch content relative to the total starch content higher than about 12 wt %, preferably higher than about 20 wt %, to improve cognitive performances, in particular memory retention, attention, concentration, vigilance and/or mental well-being in people, and particularly in a child and an adolescent. *See* abstract.

As stated in Lang: Unexpectedly, the applicants have shown that the regulation of the glycemic index, alone, was insufficient to increase these performances. The applicants have now demonstrated that certain cereal products significantly improve cognitive performance, by virtue

of the choice of appropriate proportions between slowly digestible starch and the total starch present in the product. These products may have, moreover, moderate lipid levels. *See* paragraph [0017].

The rats which consumed a biscuit-based breakfast were more calm, whereas the rats which consumed a breakfast based on ready-to-eat cereals were more active and show signs of distress (more passages in the central compartment, this indicating higher distress since the behavior of crossing a room along the diagonal rather than along the walls is unusual in rats). *See* paragraph [0073]. It is obvious that only the bioavailability of starch makes it possible to explain these differences in results. *See* paragraph [0074].

The two groups of rats respectively consume a breakfast composed of biscuits according to the invention (Lang) and cereals. *See* paragraph [0080]. The products used are balanced with respect to the supply of carbohydrates. *See* paragraph [0081].

As such, Lang discloses improving cognitive performance by consuming a breakfast combining certain proportions of slowly digestible starch with respect to the total starch of the meal. As noted in the rejection, Lang does not disclose or suggest the use of phosphatidyl serine.

Strumor

Strumor discloses stable tablets and mini-bars which dissolve in the mouth and are capable of supplying needed healthful agents. *See* column 2, lines 2-3. A wide variety of active ingredients is useful in the tablets and mini-bars of this invention. *See* column 2, lines 21-22. Of particular use, are active ingredients which are suitable for daily health conditions and those ingredients which are needed by victims of disaster to keep them alive and functioning until professional help arrives. *See* column 2, lines 21-26.

Strumor discloses 17 ingredients as useful for aiding memory, including 50 mg of phosphatidyl serine complex. *See* Example II. There is otherwise no discussion of phosphatidyl

serine complex in the specification. There is mentioned about 180 different ingredients which could be incorporated into the dissolvable product of Strumor. *See* Examples I-XI.

As such, Strumor does not disclose a dosage of phosphatidyl serine complex greater than 50 mg. Further, there is no disclosure or suggestion in Strumor to combine phosphatidyl serine with carbohydrates.

Scott and Smith

Scott (U.S. Patent Publication 2002/0150632 A1) and Smith (U.S. Patent Publication 2005/0244510 A1) are applied as above.

Present Invention

In contrast, the present invention discloses a food item, preferably a bar of chocolate, that has a phosphatidyl serine content of 100 mg to 300 mg and a relatively high carbohydrate content. *See* abstract.

The starting point of the present invention is the discovery that, in older individuals, the intake of 100 mg to 300 mg of phosphatidyl serine per day can lead to an improvement of the cognitive functional capacity, in particular the memory and learning capacity, and to an increase in the powers of concentration and attentiveness. *See* paragraph [0010].

Preferably, the food product according to the present invention has a relatively high carbohydrate content, such as fructose syrup, sugar and/or glucose syrup. By specifically combining the intake of carbohydrates and phosphatidyl serine, the glucose intake, and thus the glucose content in the brain cells, is markedly increased. In the short term, this makes possible an especially marked increase in the cognitive functional capacity. The minimum quantity of carbohydrates is preferably 15 g combined with preferably 100 to 300 mg of phosphatidyl serine. *See* paragraph [0018].

Eating one or more of the chocolate bars every day in the short term leads to an increase in the cognitive functional capacity after consumption of the bar, on the one hand, and in the long term to a lasting improvement of the cognitive functions which begins to be noticeable, for example, after a period of one to three weeks. Thus, improvements both with respect to ARCD [Age Related Cognitive Decline] and with respect to AAMI [Age Associated Memory Impairment] can be reached. *See* paragraph [0050].

Thus, the present invention is a food product that specifically combines the intake of phosphatidyl serine with the intake of carbohydrates. Applicant found this combination to improve cognitive function shortly after consumption, as well as lasting improvements over time. Neither this combination nor the results are suggested in the prior art.

Lang does not disclose the use of phosphatidyl serine to improve cognitive ability. More particularly, Lang is directed to a specific ratio of slowly digestible starch to total starch, and thus does not suggest a combination of starch with any other material.

Strumor includes phosphatidyl serine in a large list of possible beneficial materials which could be provided in dissolvable form to individuals in an emergency. There is no suggestion in Strumor to combine phosphatidyl serine with carbohydrates, particularly as there is no discussion of phosphatidyl serine at all. Further, there is no discussion of carbohydrates in Strumor.

Scott does not teach the addition of carbohydrates to his compositions. And Smith teaches the addition of carbohydrates only as necessary to prepare his formulations for administration.

Furthermore, the instant application claims priority under 35 U.S.C. § 119(e) to Austrian Patent Application A 482/2001, filed on March 26, 2001. A certified copy of this document was filed on February 15, 2008. Thus, the priority date of the instant application is March 26, 2001. The Scott reference, U.S. Patent Publication 2002/0150632 A1, is based upon provisional application 60/268,007, filed on April 12, 2001. The Smith reference, U.S. Patent Publication 2005/0244510 A1, is based upon provisional application 60/302,653, filed on July 5, 2001. Therefore, Applicant respectfully submits that Scott (U.S. Patent Publication 2002/0150632 A1)

Applicant(s): Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

and Smith (U.S. Patent Publication 2005/0244510 A1) are not prior art with regard to the instant invention.

Accordingly, Applicant respectfully submits that claims 1-13 are patentable over Lang in view of Strumor and further in view of Scott and Smith.

In light of the foregoing arguments, Applicant requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendment and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018)

Respectfully submitted,

/Katharine F. Davis Wong/

Katharine F. Davis Wong, Reg. # 51,598 for
Paul D. Bianco, Reg. # 43,500

Customer Number: 27317
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com